A Request for Continued Examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 2, 2008 has been entered.

New claim 96 is presented. Claims 67-74 and 80-87 remain under consideration.

Applicant's arguments have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are newly applied. They constitute the only rejections presently applied to the instant application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-74, 80-87 and 96 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-39 of copending Application No. 11/126062. Although the conflicting claims are not identical, they are not patentably distinct from each other because the identical pharmaceutical compositions are administered in the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 67-74, 80-87 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thor et al., US 2005/0228049.

Thor teaches combination therapy comprising GABA analogs, such as pregabalin and gabapentin, along with antimuscarinic agents, for the treatment of overactive bladder. See the Abstract, page 3, paragraph 37, page 6, paragraph 67. Antimuscarinics are characterized as the primary medication used for overactive bladder.

It is generally *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them

logically flows from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069 (CCPA 1980) and MPEP 2144.06.

An additional rationale for combining references is a clear recognition that mechanisms of action greatly differ between $\alpha_2\delta$ subunit calcium channel modulators and antimuscarinics.

With respect to claimed ratios and amounts of the active agents in the instant compositions, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). These determinations of the optimum ratios and amounts to employ with the presently claimed active agents would be within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific ratios and amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

Accordingly, one skilled in the art at the time of the invention would have been motivated to combine an $\alpha_2\delta$ subunit calcium channel modulator, as gabapentin or

pregabalin, with an antimuscarinic agent because both $\alpha_2\delta$ subunit calcium channel modulators and antimuscarinic agents are individually well-established in the prior art to treat overactive bladder.

No claim is allowed.

Maruyama et al., Journal of Pharmacology & Experimental Therapeutics, and Michel et al., Naunyn-Schmiedberg's Arch. Pharmacology, are cited to show further the state of the art with respect to the well-established utility of the antimuscarinic agents, oxybutynin, propiverine, solifenacin and tolterodine, in the treatment of overactive bladder.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 6, 2008

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614